K051977

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510(k) Summary of Safety and Effectiveness

Device:	Scorpio® X3™ UHMWPE Tibial Inserts and Scorpio® X3™ UHMWPE Patellar Components
Classification:	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Product Code	87 JWH, 87 MBH
Predicate Devices:	Scorpio® Polyethylene Tibial Inserts and Scorpio® Polyethylene Patellar Components
Contact Person:	Karen Ariemma Senior Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 (201) 831-5718 (201) 831-6038 (FAX) karen.ariemma@stryker.com
Date Summary Prepared:	September 28, 2005

Device Description

The device includes tibial and patellar components of a total knee system. These components are used for the replacement of the bearing and/or articulating surfaces of the proximal tibia and patella. The modification to the device subject of this premarket notification is the sequentially crosslinking and annealing of the UHMWPE material by a proprietary process. Tibial inserts will be made in Cruciate Retaining, Posterior Stabilized and Total Stabilizing designs. Patellar components will be made in Medialized Dome, Concentric Dome, Universal Dome, Recessed and Inset designs

Indications For Use

The Scorpio® X3™ UHMWPE Cruciate Retaining and Posterior Stabilized tibial inserts and the Scorpio® X3™ UHMWPE all polyethylene patellar components are intended to be used with cemented or cementless Scorpio femoral components, cemented or cementless Series 7000 tibial tray components and cemented Scorpio® tibial tray components in primary or revision total knee arthroplasty. The all polyethylene Scorpio® X3™ UHMWPE patellar components are intended for implantation with bone cement only.

The Scorpio® X3™ Total Stabilizer tibial inserts are intended to be used with the cemented Scorpio® TS femoral components and the cemented Scorpio® or Series 7000 tibial trays in primary or revision total knee arthroplasty.

The Scorpio® Knee System components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

Additional indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Additional indications for Total Stabilized (TS) Components:

- Severe anteroposterior and medial/lateral instability of the knee.

Summary of Data

Risk analyses and research and development testing have been performed to demonstrate equivalence of the subject products to the predicate devices. Testing and analysis includes material properties characterization, wear testing, disassembly force evaluation, multi-axis fatigue testing, patella shear testing and finite element modeling of contact stresses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2005

Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051977
Trade/Device Name: Scorpio Knee System-Tibial Inserts and Patellar Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH, MBH
Dated: July 19, 2005
Received: July 21, 2005

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051977

Device Name: Scorpio Knee System – Tibial Inserts and Patellar Components

Indications for Use:

The Scorpio® X3™ UHMWPE Cruciate Retaining and Posterior Stabilized tibial inserts and the Scorpio® X3™ UHMWPE all polyethylene patellar components are intended to be used with cemented or cementless Scorpio femoral components, cemented or cementless Series 7000 tibial tray components and cemented Scorpio® tibial tray components in primary or revision total knee arthroplasty. The all polyethylene Scorpio® X3™ UHMWPE patellar components are intended for implantation with bone cement only.

The Scorpio® X3™ Total Stabilizer tibial inserts are intended to be used with the cemented Scorpio® TS femoral components and the cemented Scorpio® or Series 7000 tibial trays in primary or revision total knee arthroplasty.

The Scorpio® Knee System components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

Additional indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament.

Additional indications for Total Stabilized (TS) Components:

- Severe anteroposterior and medial/lateral instability of the knee joint.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051977